EGAN
European Genetic Alliances' Network

"working together for a voice in research & health policies and benefiting from genetics, genomics & biotechnology"

Commissioner Janez Potocnik
European Commission
B-1040 Bruxelles
BELGIUM

11th August 2008
Re: Review of Directive 86/609

Dear Commissioner Potocnik,

I am writing to you as the President of the European Genetic Alliance Network (EGAN), an alliance of patient organisations for families affected by genetic disorders throughout Europe. EGAN has been nominated as the lead organisation on issues relating to the review of Directive 86/609 by the European Patients Forum, the voice of millions of European patients living with intractable chronic diseases.

For patients, sustained progress in high quality bio medical research offers hope of alleviating diseases that currently reduce the quality (and often the quantity) of their lives. Quite apart from the human cost of these diseases, their economic and social costs are a burden for society as a whole. Animal research is an essential component of the search for new medicines that are safe, effective and fit for purpose. Properly regulated, ethically supervised animal research has led to advances in science and medicine that have transformed the lives of those affected by diseases hitherto incurable.

For patients and families affected by life limiting diseases, it is not the use of animals per se which is of concern. Rather it is the fact that a regulatory regime that creates excessive barriers to their use is doing so at a huge human cost. Where alternative methods allow to make scientific advances that are equal or superior, in quality and speed and where those methods can be used, at equivalent cost (or cheaper), we endorse them unreservedly. However, this is not generally the case yet. Therefore research using animals is still essential for sustained progress towards innovative therapies, and patients continue to suffer consequences of their disease that might otherwise have become avoidable.

Against this background, it is our understanding that there are, a number of proposals in the current draft of the revision that cause us concern, in particular the reporting provisions for genetically modified animals, and the restrictions on the use of great apes and non human primates.

Genetically modified animals are invaluable tools for researchers investigating a wide range of diseases, including cancer, heart disease, obesity and many single gene disorders such as cystic fibrosis and muscular dystrophy. As a result, patients have benefited from new therapies and better management of their conditions. The vital role these animals play in research is poorly understood by the public. In the media and by those opposed in principle to animal research, they are often portrayed as somehow sinister and threatening. A requirement for reporting to include non genetically modified offspring of transgenic breeding programmes would artificially inflate the figures, exacerbating the issue in the public mind. Basic research with these animal models into the fundamental biology of disease processes is often co-funded by patient charities (NGOs), publicly funded bodies and the private sector. The present reporting requirement would make such research more difficult, and potentially delay the development of novel therapies.

The use of non human primates rightly raises sensitivities that must be taken into consideration when regulating research. However, this sensitivity should be balanced against the suffering of people living with serious diseases and against the consequences for them should there be overly strict prohibitions on the use of non-human primates.

Without non human primates the development of monoclonal antibodies would not have been possible, and many late stage developments in oncology would be stalled. Therapies for conditions such as diabetes (imperfectly managed for many with currently available therapies, and a major cause of adult onset disabilities such as blindness) would be delayed. Vaccines to counter future health scourges may not become available in a timely manner, rendering European citizens vulnerable to resurgent infectious diseases or novel threats arising from inter-species transmission of pathogens. Rather than overly codifying the situations in which non-human primates may be used, and thereby creating barriers to progress, we would propose that the revised directive requires the researcher to demonstrate why proposed work with non human primates was not feasible using other methods, with the knowledge and technological possibilities prevailing at the time of the application.

Research using great apes has yielded significant advances in the past and may provide future opportunities for addressing global health issues (such as the need for an HIV vaccine, or for progress in gene and stem cell therapies). An absolute ban on their use would irrevocably block any future research on them and force such research into other jurisdictions with perhaps less transparency and less rigorous welfare requirements. This is not to argue for a “carte blanche” for researchers, but rather to ask that the door be left open to the possibility of using great apes in research in the future should a pressing need arise.

Our concern, as patients, is that undue barriers to scientific research will inhibit progress. Appropriate, proportionate regulation should adequately consider the plight of those living with the consequences of unmet medical needs alongside the welfare of animals upon which research is performed. An overly restrictive regulatory framework will prolong patients’ suffering. If research is forced out of Europe, the links between patients and the research community – in academia, in clinical medicine and in industry - will be broken. This will weaken European research and retard progress towards novel means for managing life limiting diseases.

We understand that others have concerns about aspects of the proposed revision of 86/609 such as limitations on the re-use of animals, the timetable for a shift to captive bred non-human primates and the transparency provision for reporting animal use. We do not have a formal position on these issues as they are technical and practical in nature. However, we would be opposed to any unnecessary barriers that may hinder or prevent desirable, ethically sound, high quality biomedical animal research to alleviate unmet medical diseases and improve the lives of millions of European patients. We would therefore urge you to consider the arguments put forward by others on these issues as well as the points we raise above in order to ensure a positive environment for animal based research in the EU.

Yours sincerely,

Alastair Kent
President EGAN

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